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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,856	03/23/2004	Andrew B. Sparks	061834-5028-US	6556

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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT PAPER NUMBER

1639

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/807,856	SPARKS ET AL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,42 and 103-109 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,42 and 103-109 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/23/04; 4/20/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

5.00

### **DETAILED ACTION**

1. Claims 1, 42, 103-109 are pending and examined.

### ***Election/Restrictions***

2. Applicant's election of 6 to 60 amino acid; biotinylated recognition units and avidin or streptavidin; and recombinant bacteriophage in the reply filed on 4/20/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Applicant points out that biotinylated recognition units and avidin or streptavidin is not recited in claim 1, and request clarification. The examiner agrees that biotinylated recognition units and avidin or streptavidin are not recited in claim 1.

### ***Priority***

4. This application is a divisional of co-pending U.S. patent application Serial No. 08/630,915 filed April 3, 1996, now which is a continuation-in-part of abandoned U.S. Patent Application Serial No. 08/417,872 filed April 7, 1995, the entire contents of which are incorporated herein by reference. The first line of specification, however, does not appear to have been amended to claim priority as a divisional of 09/879,957, filed

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6/13/2001, now U.S. Patent 6,309,820, (see preliminary amendment, entered 6/24/2004), as is necessary to claim priority under 35 USC 120.

***Information Disclosure Statement***

5. The IDS filed 3/23/2004 and 4/20/2005, appear in large measure to be duplicative. Both of said IDS have been considered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 42, 103-109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is for lack of written description.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention. Applicant's claims are directed to a method of identifying a polypeptide using a multivalent recognition unit complex. The claims also recite that the binding specificity of the recognition unit has *decreased* by incorporation

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of the unit into the complex. The specification discloses the preparation and use of only very limited numbers of "multivalent recognition unit complexes" and provides only a vague showing that binding specificity of the exemplified recognition units has been decreased by complexation. There is no description of how one is to achieve this decreased specificity with any "multivalent recognition unit complex". Further, the claimed "recognition unit" is not specifically described in the specification (i.e. only a general definition is given, see instant specification at p. 32-33) and the general terminology would encompass an enormous number of peptide sequences that are quite diverse in structure. The disclosure is neither representative of the claimed genus, which encompasses a vast variety of "recognition units" and "multivalent recognition unit complexes", nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members which are yet to be prepared or envisioned. This further evidences that the instant specification lacks written description for the claimed genus or a substantial portion thereof.

7. Claims 1, 42, 103-109 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "recognition units" comprising SH2 or SH3 domains, does not reasonably provide enablement for any "recognition unit". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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It is clear from applicant's specification how one of skill in the art might practice this invention when the "recognition units" comprise SH2 or SH3 domains; however, there is insufficient guidance as to how to make and use any "recognition unit". There are many factors be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether undue experiment is necessitated. These factors can include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the relative skill of those in the art;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1 and 2) The breadth of the claims and the nature of the invention: The claims recite a "recognition units" and or "multivalent recognition unit complex". The recognition units are any peptides 6-60 amino acids in length which "selectively bind a domain of interest". This represents a very broad scope. The invention is drawn to a method for identifying a polypeptide where a "multivalent recognition unit complex" is used. The binding specificity of the units making up the "multivalent recognition unit complex" must be "*decreased*" by incorporating them into the complex.

(3 and 5) The state of the prior art and the level of predictability in the art While such screening assays and multivalent complexes were well known at the time of filing,

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the state of the art was such that one of skill would be unable to predict if the binding specificity of the recognition unit would be decreased by incorporation of the unit into the complex. . See further discussion below.

(4) The level of one or ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, *given its unpredictability*, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have provided very few examples of "recognition units" and or "multivalent recognition unit complexes" and even fewer examples of the decreased binding specificity; therefore further research would be necessary to make or use the invention for the full scope of the claims due to the high unpredictability in the art. See MPEP 2164.03: "[I]f little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling." Also, "in application directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims." *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24, (CCPA 1970)". If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On

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the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. MPEP 2164.03.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The specification given no guidance to permit one of skill in the art to devise strategies to make and use *any* "recognition units" and/or "multiple recognition unit complexes" to identify a polypeptide of interest, where the binding specificity of the "multivalent recognition unit complexes" is *decreased* over a "recognition unit" alone. The structures of possible variants of both of these entities are sufficiently diverse as to require research into methods for making and using such. Since a generalized scheme for making and using the "recognition units" and /or "multivalent recognition unit complexes" as claimed is not provided, one is left to guess as to what scheme might be used. As stated above, these specific techniques were not routine in the art at the time of filing and would have a high degree of unpredictability. Moreover, the instant specification give one skilled in the art no indication that one could use any such entity and have a reasonable expectation of success. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach one of skill how to make and use the invention as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 and n.23, 20 USPQ2d 1438, 1455 and n.23 (Fed. Cir. 1991). Therefore, the practice of the full scope of the invention would require undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:



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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 42, 103-109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims include a limitation reciting that the binding specificity is "decreased". This is a relative term which renders the claims indefinite. The term is not defined by the claims and of skill in the art would not be reasonably apprised of the metes and bounds of the invention. It is unclear what value the binding affinity has been "decreased" from (i.e., that of a single recognition unit or multiple recognition units). There is also confusion about the term "decreased" when taken in light of the instant specification. One of skill would most likely interpret "decrease" to mean "lowered"; however the instant specification seems to also imply that "broadened" is meant (see page 88, lines 28-31 of the instant specification).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 42, 103-109 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6309820 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention, drawn to a method of identifying a polypeptide comprising a domain of interest, comprising: (a) contacting a multivalent recognition unit complex with a plurality of polypeptides from a cDNA expression library, in which the recognition units are peptides having in the range of 6 to 60 amino acid residues and which selectively bind a domain of interest; and (b) identifying a polypeptide having a selective binding affinity for said recognition unit complex; wherein the binding specificity of the recognition units have been decreased by incorporating said recognition unit into said multivalent recognition unit complex, and variations thereof, encompass the claims of **U.S. Patent No. 6309820 B1**, drawn to a method of identifying a polypeptide comprising an *SH3* domain of interest, comprising (a) contacting a multivalent recognition unit complex with a plurality of polypeptides from a cDNA expression library, in which the recognition units are peptides having in the range of 6 to 60 amino acid residues and which selectively bind an SH3 domain; and (b) identifying a polypeptide having a selective binding affinity for said recognition unit complex; wherein the binding specificity of the recognition units has been decreased by incorporating said recognition unit into said multivalent recognition unit complex.

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10. Claims 1, 42, 103-109 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,709,821 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention, drawn to a method of identifying a polypeptide comprising a domain of interest, comprising: (a) contacting a multivalent recognition unit complex with a plurality of polypeptides from a cDNA expression library, in which the recognition units are peptides having in the range of 6 to 60 amino acid residues and which selectively bind a domain of interest; and (b) identifying a polypeptide having a selective binding affinity for said recognition unit complex; wherein the binding specificity of the recognition units have been decreased by incorporating said recognition unit into said multivalent recognition unit complex, and variations thereof, encompass the claims of **U.S. Patent No. 6,709,821 B2**, drawn to a method of identifying a polypeptide comprising an *SH2 domain* of interest comprising: (a) contacting a multivalent recognition unit complex with a plurality of polypeptides from a cDNA expression library, in which the recognition units are peptides having in the range 6 to 60 amino acid residues and which selectively bind an SH2 domain; and (b) identifying a polypeptide having a selective binding affinity for said recognition unit complex wherein the binding specificity of the recognition units has been decreased by incorporating said recognition units into said multivalent recognition unit complex.

### ***Conclusion***


11. Claims 1, 42, 103-109 are rejected.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Mark L. Shibuya  
Examiner  
Art Unit 1639

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